REMARKS

The specification has been amended to clarify that the present case is a continuation, rather than a divisional, application of the parent application. Sequence identification numbers have been added, as well as a sequence listing.

Claims 54 and 58 have been amended to exactly track the language of claim 1 in the parent patent (U.S. Patent No. 6,740,497), thereby clarifying these claims. Claims 62 and 63 are identical to allowed claim 2 in the parent patent (U.S. Patent No. 6,740,497). No new matter has been added.

Request for Reconsideration

Applicants would like to thank the Examiner for indicating that the claims are free of the prior art.

The rejections of the claims under 35 U.S.C. § 112, first paragraph (both written description and enablement), are respectfully traversed. The present application contains examples, which both demonstrates possession of the invention at the time of filing, meeting the written description requirement, and provides all the parts necessary for carrying out the invention, meeting the enablement requirement. Furthermore, the office has failed explain *why* it doubts the truth or accuracy of any statement in the supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement, as required to support a rejection under section 112, first paragraph.

The office has assertion that: "Applicants have not provided any description, sequence or structure for any oncoprotein substrate to be used in the claimed methods. Applicants have also not provided any guidance for identifying or preparing such substrates." on page 3 of the office action. This statement is incorrect.

The specification provides details on how to make and use the present invention, starting on page 10 of the specification. Reporter molecules may be based on the proteins which are natural substrates for the chemical reactions to be measured (page 14, lines 19-21). More than 120 oncogenes are known, and many of them are known to be kinases – and therefore their natural protein or peptide substrates are known (page 7, lines 12-21). Peptides which mimic the protein that is the natural substrate,

displaying a particular order or pattern of amino acid residues, may be used (page 11, line 19 to page 12, line 11). Modification of the proteins or peptides is described (page 13, line 6 to page 14, line 5). Fusion proteins of GFP are described (page 15, lines 1-19). Reporter molecules for non-kinase oncogenes are describe (page 14, lines 6-21). Peptides, as model substrates, are used in the examples. Detailed examples, using these model substrates, are provided. Applicants submit that how to make and use the claimed invention is described, is sufficient detail for one of ordinary skill in the art to make and use the claimed invention, without undue experimentation. Furthermore, the examples demonstrate that applicants were in possession of the invention. Finally, all the elements that one would need to carry out the claimed invention are included in the claims of the parent application which is an allowed patent, presumed to be enabled and meet the written description requirement.

A specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose. M.P.E.P. § 2163 (II)(A)(3)(a) citing *Cooper v. Goldfarb*, 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998). An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention. M.P.E.P. § 2163 (II)(A)(3)(a). A single working example in the specification for a claimed invention is enough to preclude a rejection which states that nothing is enabled since at least that embodiment would be enabled. M.P.E.P. § 2164.02. Furthermore, a specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support: "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement."

M.P.E.P. § 2164.04, citing *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The office has failed to explain why it doubts the truth or accuracy of any statement in the specification; rather the office has only pointed out that the description is insufficient. Withdrawal of these grounds of rejection is respectfully requested.

The rejection of claims 54-57 under 35 U.S.C. § 112, first paragraph (enablement), is respectfully traversed. By definition, an oncogene is a causative factor in initiating cancerous growth, and cancer is defined as that growth.

The definition of oncogene is "any gene that is a causative factor in the initiation of cancerous growth" (Webster's New Universal Unabridged Dictionary, 1996, Barnes & Noble Books). Furthermore, the presence of a cancerous growth is cancer. Therefore, if an oncogene is active, it causes cancer.

The citations provided are not inconsistent with this conclusion. First, tumor suppressor genes are not oncogenes, since their absence or lack of activity results in cancer; rather oncogenes encourage cell growth (see http://rex.nci.nih.gov/massmedia/CANCER RESRCH WEBSITE/CANCER RESRCH MAIN.htm, cited in the Office Action). Mutated or excess copies of oncogenes result in altered or excess protein and too much cell growth (ibid.). Therefore, the activity of the oncogene would be the activity of the mutated gene or the presence of the excess protein – otherwise the gene would not be "a causative factor in the initiation of cancerous growth" as required by the definition of oncogene. Withdrawal of this ground of rejection is respectfully requested.

The rejection of the claims under 35 U.S.C. § 112, second paragraph, is respectfully traversed. The claims have been amended for consistency of language. Furthermore, the metes and bounds of the claims are clear. The present specification clearly indicates that determining the presence of said chemical reaction is an indication of cancer or an indication of a lack of anti-cancer activity; relation back to the preamble of the claims is not required to render the metes and bounds of the claims clear. No essential steps have been omitted. Withdrawal of this ground of rejection is respectfully requested.

The objection to the oath or declaration has been obviated by the filing of a supplemental Application Data Sheet.

The objection to the specification has been obviated by amendment, including a sequence listing. CRF and paper versions of the Sequence Listing are provided herewith. Applicants hereby state that the contents of the CRF and the paper versions of the Sequence Listing are identical.

The rejection of the claims under the doctrine of obviousness-type double patenting is respectfully traversed. The office has failed to provide a motivation to modify claims 1 and 16 of U.S. Patent No. 6,7740,497, to a method of detecting cancer or a method of testing a compound for anticancer activity.

As noted in M.P.E.P. § 804 II. B. 1.:

> A double patenting rejection of the obviousness-type is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103" except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).
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> Since the analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection, the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obvious-type double patenting analysis.
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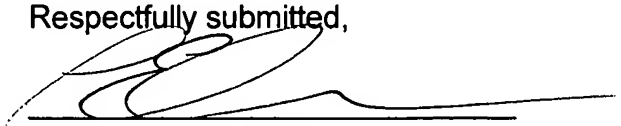
> When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art.

The office has stated that "[o]ne of ordinary skill in the art would have recognized that" the patented methods could be used for detecting cancer or testing a compound for anticancer activity, however the office has failed to set forth *motivation* for detecting cancer or testing a compound for anticancer activity by the patented methods. Applicants submit that the obviousness-type double patenting rejection is improper. Withdrawal of this ground of rejection is respectfully requested.

Respectfully submitted,



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